I. AMENDMENTS

A. Amendments To The Specification

Please amend the specification as follows.

Please replace the paragraph appearing on page 16, from line 21 to page 17, line 6 with the following:

Figure 18 shows an array of two inventive radial inserts (202) in conjunction with two circumferentially placed intrastromal segments (239). The radial inserts (202) are placed in the cornea for the purposes noted above, typically hyperopia correction and perhaps astigmatism correction, and the circumferential segments (239) are introduced for myopia or astigmatism correction. A complete disclosure of the structure and use of the segments (239) may be found in U.S. Patent application Nos. 08/101,438, entitled SEGMENTED PREFORMED INTRASTROMAL CORNEAL INSERT, filed August 2, 1993 and 08/101,440, entitled SEGMENTED PLIABLE INTRASTROMAL CORNEAL INSERT, filed August 2, 1993, both by Silvestrini, the entirety of which are incorporated by notice. The specific array of radial inserts (202) and circumferential segments (239) is not limited to the alternating pattern shown in the Figure, nor is the invention limited to the positioning or numbers of inserts shown in the Figure. The choice of and placement of appropriate ~~insets~~ inserts and segments is left to the attending health professional based upon the abnormality to be treated.

Please replace the paragraph appearing on page 19, from line 18 to line 23 with the following:

Figure 19B shows the inner cavity (264) which may be filled with a biologic, a drug or other liquid, or biologically active eye treatment material. These devices may be tied or pinched or crimped or otherwise closed, typically at their point of insertion, by known techniques. If the inserts were closed or sealed prior to introduction, the insert ~~my~~ may later be punctured with a syringe and a fluid or gel ~~my~~ may be introduced or withdrawn for a variety of clinical reasons.

Please replace the paragraphs appearing on page 24, line 23 through page 26, line 16, with the following:

Spreader (150) includes handle (152), extension (154), and tip (156). To provide increased rotational control of spreader (150), a portion of handle (152) is knurled and cutouts (153) are provided in opposing positions for marking the instrument. Extension (154) has a much smaller outside diameter than handle (152), and has a tapering outside diameter that gradually decreases toward the end of extension (154) that joins with tip (156).

Tip (156) is substantially flat and relatively wide and thin as observed in a comparison of Figures 36A and 36B. Tip (156) extends from extension (154) at an obtuse angle (13) to the longitudinal axis of extension (154) and handle (152), as shown in Figure 36A. The obtuse angle provides the user with a comfortable handle position when tip (156) is inserted into the incision. Tip (156) has a tapering thickness **t** which decreases in the direction from the extension (154) to tip end (158).

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As shown in Figure 36B, tip end (158) is rounded and is preferably substantially hemispherical, although greater and lesser radii of curvature may be employed to define the tip end. Importantly, the tip end is not knife sharp, but rather, is relatively blunt so as to function to separate tissue along layers, but not to cut. Tip end (158) transitions into tip sides (160) as the curvature of tip end (158) gradually straightens into the substantially straight edges of tip sides (160). Tip sides (160) are sharp, although not knife sharp. A comparison of the relatively dull edge of tip end (158) and the relatively sharp edges of tip sides (160) can be seen by comparing the sectional views of Figures 36C and 36D, respectively.

With the arrangement of stromal spreader tip (156) as described, the relatively dull, slightly rounded tip end (158) greatly reduces the risk of perforation of the corneal tissues upon insertion of the tip into the incision. Additionally, by rotating the spreader using handle (152) the stromal layers ~~are~~ can be effectively separated to form a pocket, or enlarge or otherwise modify an initial pocket created by the corneal pocketing tool described above.

Figure 36E illustrates, in an exaggerated way, the transition between blunt tip end (158) and the relatively sharp edge of tip side (160), which supports the fact that the insertion of the tip presents a relatively low risk of perforation of the stromal tissues. Once the spreader has been inserted, separation can begin through use of sharper side edges (160), together with blunt tip end (158).

Figure 36F shows a variation of the tip shown in Figure 36A. In this variation, the joinder of tip (156) and extension (154) is formed at the obtuse angle β to the longitudinal axis of extension (154 and handle (152), the same as shown in Figure 36A. However, the majority of the tip that is distal to the joinder of the tip and the extension, i.e., tip (156') is formed at an angle γ with regard to the longitudinal axis of extension (154) and handle (152), and where angle γ is an obtuse angle that is less than obtuse angle β. The remaining features of tip (156') are essentially the same as those described above with regard to tip (156) in Figures 36A-36E.

Preferably, the handle is oriented relative to the tip in such a way as to provide the surgeon with optimal visual and manual access to the surgical site. Figures 37-38B illustrate an alternative handle orientation. Figure 37 illustrates a partial front view of spreader (170) having handle (176), extension (172) and spreader tip (174). Handle (176) may be at an angle (171) relative to the plane of spreader tip (174). Angle (171) is typically between about 20° to about 110°, more preferably between about 40° to about 70°, most preferably 60°.

Figures 38A and 38B show partial top views of spreader (170) illustrating a single spreader tip construction (174) and a double spreader tip construction (177), (178) respectively. Because the single tip construction is asymmetrical, it may be desirable to have two opposite-handed instruments available for use depending on surgeon preference. The construction of Figure 38B eliminates this need for two separate instruments. The spreader tips of Figures 37-38B may have any of the constructions described above.

Please replace the paragraph appearing on page 36, lines 14 through 22, with the following:

Of course, as noted above with regard to the pocket forming tool, a number of arcuate members may be provided, each having an arc length to extend a desired distance from the initial incision. ~~Preferrably~~ Preferably, the arc length of the arcuate member of the positioning instrument will be a little anger than the distance from the incision to the radial pocket of interest. For example, with radial pockets at 30°, 90° and 150°, arc lengths for the arcuate member of the positioning instrument may be 50°, 110°, and 170°. The added length is useful in case a segment is pushed beyond the radial pocket and it is necessary to hook on the far side of the insert to pull it back towards the incision.

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B. Amendment Of The Abstract

Please replace the abstract with the following amended abstract appearing on page 48 of the original application papers.

The subject invention relates to an intrastromal corneal insert designed to be meridionally situated in an interlamellar pocket or channel made within the cornea of a mammalian eye. The insert has a shape which, when inserted into the cornea, has a significant meridional dimension and may be used to adjust corneal curvature and thereby correct or improve vision abnormalities such as hyperopia. The inserts ~~may~~ also have a circumferential component to their configuration to allow concurrent correction of other vision abnormalities. The radial insert ~~may be made of a physiologically compatible material, e.g., one or more synthetic or natural, soft, firm, or gelatinous polymers. In addition, the insert~~ or segment may be used to deliver therapeutic or diagnostic agents to the corneal interior or to the interior of the eye.

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~~One or more of the radial inserts of this invention typically are inserted into the cornea so that each subtends a portion of the meridian of the cornea outside of the cornea's central area, e.g., the area through which vision is achieved, but within the cornea's frontal diameter. Typically, the insert is used in arrays of two or more to correct specific visual abnormalities, but may be used in isolation when such is called for. The invention also includes both a minimally~~

E5 ~~invasive procedure for inserting one or more of the devices into the cornea using procedures beginning within the cornea as well as procedures beginning in the sclera.~~